Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Page: 4

Report Date:04/29/2009

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical	
				Ma	ale			
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058810503 052000705 059902303 059902005	04/22/02 08/18/04 03/25/02 04/09/03	729 727 729 727	50 (3) 49 (3) 50 (3) 50 (3)	35(702) 34(692) 29(683) 39(685)	521.9 515.2 501.9 514.9	Isoeugenol Kava kava extract beta-Myrcene Pulegone	
				Fen	nale			
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058810503 052000705 059902303 059902005	04/23/02 08/19/04 03/26/02 04/10/03	730 728 730 728	50 (5) 50 (5) 50 (5) 50 (5)	33(699) 34(683) 31(668) 31(682)	339.3 354.3 323.8 341.2	Isoeugenol Kava kava extract beta-Myrcene Pulegone	

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

l Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#All Organs: Benign Tumors								
3		49/50 (98%) 47/50 (94%)	49/49 (100%)	49/50 (98%)		41/50 (82%) 42/50 (84%)	43/50 (86%)	40/50 (80%)
Overall Incidence	Total	194/199 (97.49%)	Mean 97.5%	SD 2.52%	Total	166/200 (83%)	Mean 83%	SD 2.58%
#All Organs: Malignant Tumors			•••••				•••••	
-		29/50 (58%) 10/50 (20%)	17/49 (35%)	23/50 (46%)		18/50 (36%) 8/50 (16%)	11/50 (22%)	11/50 (22%)
Overall Incidence	Total	79/199 (39.7%)	Mean 39.67%	SD 16.2%	Total	48/200 (24%)	Mean 24%	SD 8.49%
#All Organs: Malignant and Benign Tu	ımors							
		50/50 (100%) 47/50 (94%)	49/49 (100%)	50/50 (100%)		46/50 (92%) 44/50 (88%)	46/50 (92%)	45/50 (90%)
Overall Incidence	Total	196/199 (98.49%)	Mean 98.5%	SD 3%	Total	181/200 (90.5%)	Mean 90.5%	SD 1.91%
#All Organs: Hemangioma			•••••				•••••	
-		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#All Organs: Hemangiosarcoma								
		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	2/200 (1%)	Mean 1%	SD 2%

^{*:} Denominator is number of animals with tissues examined microscopically

Page: 5

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 6 Report Date:04/29/2009

Species: RATS Strain: F344

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: GAVAGE Vehicle: CORN OIL

				Ma	ale						Fem	ale		
All Organs:	manaiama													
Hemangiosarcoma or He	mangioma	1/50	(2%)	0/49	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)	0/10	(070)	0/00	(070)		2/50	(4%)	0,00	(070)	1,00	(270)
Overall Incidence	Total	1/199	,		0.5%	SD		Total		(1.5%)		n 1.5%		1.91%
All Organs: Histiocytic Sarcoma														
		0/50 0/50	(0%) (0%)	0/49	(0%)	1/50	(2%)		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/199	(0.5%)	Mean	0.5%	SD	1%	Total	0/200	(0%)	Mea	n 0%	SD	0%
All Organs: Leukemia: Erythrocytic					• • • • • • • • • • • • • • • • • • • •	•••••			•••••	•••••	• • • • • • • • • • • • • • • • • • • •		• • • • • • • • • • • • • • • • • • • •	
		0/50 0/50	(0%) (0%)	0/49	(0%)	0/50	(0%)		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/199	(0%)	Mean	0%	SD () %	Total	0/200	` '	Mea	n 0%	SD	0%
#All Organs: Leukemia: Lymphocytic, Undifferentiated	Monocytic, N	lononuclea	ar, or						••••••					
		10/50 4/50	(20%) (8%)	7/49	(14%)	9/50	(18%)		8/50 4/50	(16%) (8%)	5/50	(10%)	5/50	(10%)
Overall Incidence	Total		(15.08%)	Mean	15.07%	SD :	5.28%	Total	22/200	` '	Mea	n 11%	SD	3.46%
#All Organs: Malignant Lymphoma: Hi or Undifferentiated Cell T		nphocytic, 0/50 0/50	Mixed, NOS, (0%) (0%)	1/49	(2%)	1/50	(2%)		0/50 0/50	(0%) (0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total		(0%)		1.01%	0.0	1.17%	Total		(0.5%)		n 0.5%	SD	40/

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
All Organs: Mesothelioma: Benign								
_		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Mesothelioma: Benign, Mali						•••••	•••••	
-		3/50 (6%) 2/50 (4%)	3/49 (6%)	2/50 (4%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	10/199 (5.03%)	Mean 5.03%	SD 1.19%	Total	2/200 (1%)	Mean 1%	SD 1.15%
All Organs: Mesothelioma: Malignant								
Ū		3/50 (6%) 2/50 (4%)	3/49 (6%)	2/50 (4%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	10/199 (5.03%)	Mean 5.03%	SD 1.19%	Total	2/200 (1%)	Mean 1%	SD 1.15%
All Organs: Osteoma						•••••		
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma	•••••							
		2/50 (4%) 0/50 (0%)	1/49 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2.01%	SD 1.63%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

Page: 7

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Page: 8

Report Date:04/29/2009

Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
All Organs: Osteosarcoma or Osteoma	<u> </u>							
		2/50 (4%) 0/50 (0%)	1/49 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2.01%	SD 1.63%	Total	0/200 (0%)	Mean 0%	SD 0%
Adrenal Cortex: Adenoma				•••••				•••••
		0/50 (0%) 2/50 (4%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%	Total	0/200 (0%)	Mean 0%	SD 0%
Adrenal Cortex: Carcinoma					•••••			
		0/50 (0%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Ganglioneuroma				•••••				•••••
•		0/50 (0%) 0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Hemangioma				•••••				
3		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Adrenal Medulla: Pheochromocytoma Benign 5/50 (10%)(10%)(22%)2/50 (4%)(6%)(2%)8/50 (16%)3/50 (6%)29/199 (14.57%) 9/200 (4.5%) Overall Incidence Total Mean 14.55% SD 5.69% Total Mean 4.5% SD 1.91% *Adrenal Medulla: **Pheochromocytoma Complex** 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% 0/199 (0%) *Adrenal Medulla: Pheochromocytoma Malignant 3/50 (6%)(0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 3% SD 0% Total 5/199 (2.51%) Mean 2.5% Total 0/200 (0%) Mean 0% *Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS 7/50 (14%)(10%)(26%)(6%)1/50 (2%)8/50 (16%)3/50 (6%)**Overall Incidence** 33/199 (16.58%) SD 6.74% SD 1.91% Total Mean 16.55% Total 9/200 (4.5%) Mean 4.5% #Bone: Chondrosarcoma 0/50 (0%)0/49 0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/199 (0%)Mean 0% SD 0% Total 0/200 (0%)Mean 0% SD 0%

Page: 9

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 10

			Male				Female	
#Bone: Chondrosarcoma or Cl	hondroma	0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Chordoma				1/50 (2%)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 1/199 (0.5%)	0/49 (0%) Mean 0.5%	SD 1%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Osteoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma								
		2/50 (4%) 0/50 (0%)	1/49 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2.01%	SD 1.63%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma or Oste								
		2/50 (4%) 0/50 (0%)	1/49 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2.01%	SD 1.63%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 11

			Male				Female	
*Brain: Astrocytoma Malignant		0/50 (00/)	0/40 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%) 1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Ependymoma Benign								•••••
		0/50 (0%) 0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Ependymoma Malignant	•••••							
. ,		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Glioma Malignant					•••••			
3		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Granular Cell Tumor Benig								
2.2	y	0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 12

			Male				Female	
Brain: Medulloblastoma Mal								
Meduliobiastonia Mai		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Meningioma Malignant								•••••
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Meningioma: Benign, Ma	lignant, NOS		(00)	(004)		0.50		(201)
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma Beniq								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma Malig								
		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

JII. May2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 13

			Male				Female	
Brain:								
Oligodendroglioma, Gli	oma, or Astroc							
		1/50 (2%) 1/50 (2%)	0/49 (0%)	1/50 (2%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Brain: Osteosarcoma			•••••	•••••		•••••		•••••
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Schwannoma Malignan	t				•••••			
Ç		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Adenoma			•••••					
		2/50 (4%) 3/50 (6%)	0/49 (0%)	5/50 (10%)		3/48 (6%) 3/50 (6%)	2/50 (4%)	7/50 (14%)
Overall Incidence	Total	10/199 (5.03%)	Mean 5%	SD 4.16%	Total	15/198 (7.58%)	Mean 7.56%	SD 4.41%
Clitoral/Preputial Gland: Carcinoma								
		2/50 (4%) 1/50 (2%)	1/49 (2%)	0/50 (0%)		2/48 (4%) 0/50 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2.01%	SD 1.63%	Total	4/198 (2.02%)	Mean 2.04%	SD 2.36%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Clitoral/Preputial Gland: Carcinoma or Adenoma 4/50 (2%)(10%)5/48 (10%)(8%)(14%)(8%) 4/50 3/50 (6%)SD 3.44% **Overall Incidence** Total 14/199 (7.04%) Mean 7.01% Total 19/198 (9.6%) Mean 9.6% SD 3.44% *Clitoral/Preputial Gland: **Fibrosarcoma** 0/50 (0%)0/48 (0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% Total 0/198 (0%) Mean 0% SD 0% 0/199 (0%) *Clitoral/Preputial Gland: Sarcoma 0/50 (0%)(0%)(0%)0/48 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/199 (0%) Mean 0% Total 0/198 (0%) Mean 0% *Clitoral/Preputial Gland: Squamous Cell Papilloma 0/50 (0%)(0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/199 (0%) SD 0% 0/198 (0%) SD 0% Total Mean 0% Total Mean 0% #Ear: **Neural Crest Tumor** (0%)0/50 0/49 (0%)0/50 0/50 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/199 (0%)Mean 0% SD 0% Total 1/200 (0.5%)Mean 0.5% SD 1%

Page: 14

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Esophagus: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Esophagus: Lipoma	•••••							
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Eye: Amelanotic Melanoma, Bei								
, , , , , , , , , , , , , , , , , , , ,	3	0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Eye: Melanoma Malignant								
-		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Eye: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

Page: 15

^{#:} Denominator is number of animals necropsied

ni. May2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 16

			Male				Female	
Harderian Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Harderian Gland: Carcinoma or Adenoma								•••••
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Heart: Schwannoma Benign	•••••							
•		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Heart: Schwannoma Malignant								
-		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Large: Colon/Rectun Adenoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Intestine Large: Colon/Rectur	m:							
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectur Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectur								
-		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Leiomyoma								
•		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

Page: 17

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Intestine Small: Jejunum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Granular Cell Tumor M								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Leiomyoma					•••••			
·		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
ntestine Small: Jejunum: Leiomyosarcoma								
·		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
ntestine Small: Site Unsp								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

Page: 18

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Intestine Small: Site Unsp								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp						•••••	•••••	•••••
	_	0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Leiomyoma	pecified:							
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Leiomyosarcoma	pecified:							
·		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma							•••••	
		4/50 (8%) 2/50 (4%)	4/49 (8%)	2/50 (4%)		0/50 (0%) 1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	12/199 (6.03%)	Mean 6.04%	SD 2.36%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

Page: 19

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 20

Report Date: 04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Islets, Pancreatic: Carcinoma 0/50 (0%)0/49 (0%)(2%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 **Overall Incidence** Total 1/199 (0.5%) Mean 0.5% SD 1% Total 0/200 (0%) Mean 0% SD 0% *Islets. Pancreatic: Carcinoma or Adenoma 4/50 (8%)(6%)0/50 (0%)(2%)(2%)2/50 (4%)1/50 (2%)**Overall Incidence** Total 13/199 (6.53%)Mean 6.54% SD 1.96% Total 3/200 (1.5%) Mean 1.5% SD 1% *Kidney: Pelvis and Transitional Epithelium: Carcinoma 0/50 (0%)(0%)(2%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 1% SD 0% Total 1/199 (0.5%) Mean 0.5% Total 0/200 (0%) Mean 0% *Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 1/199 (0.5%) Mean 0.5% SD 1% SD 0% Total Total 0/200 (0%) Mean 0% *Kidney: Pelvis and Transitional Epithelium: **Papilloma** 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/199 (0%)Mean 0% SD 0% Total 0/200 (0%)Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

11. May2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 21

			Male				Female	
Kidney: Renal Tubule: Adenoma								
		0/50 (0%) 1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma				•••••				
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%) 1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Hemangiosarcoma								
•		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Lipoma	•••••							
F		0/50 (0%) 0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Page: 22

Report Date:04/29/2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344 Vehicle: CORN OIL Length of Study: CHRONIC

			Male				Female	
Kidney: Renal Tubule: Mesenchymal Tumor Be	nign							
·		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Nephroblastoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Kidney: Renal Tubule: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
_iver: Cholangioma							•••••	•••••
•		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Liver: Hemangiosarcoma								
•		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

1. Way 2000

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 23

			Male				Female	
Liver: Hepatocellular Adenoma								
·		1/50 (2%) 1/50 (2%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.51%	SD 1.01%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Liver: Hepatocellular Carcinom	a	•••••		•••••				
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Carcinom	a or Hepatob	0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/199 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Carcinom	a or Hepatoc	ellular Adenoma 1/50 (2%) 1/50 (2%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.51%	SD 1.01%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Liver: Hepatocellular Carcinom Hepatoblastoma	a, Hepatocell	lular Adenoma, or						
		1/50 (2%) 1/50 (2%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.51%	SD 1.01%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 24

Report Date:04/29/2009

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

				Ma	ale						Fem	ale		
*Lung: Alveolar/Bronchiolar Adenoi	ma													
		3/50 0/50	(6%) (0%)	2/49	(4%)	3/50	(6%)		1/50 2/50	(2%) (4%)	0/50	(0%)	4/50	(8%)
Overall Incidence	Total		(4.02%)	Mean	4.02%	SD	2.83%	Total	7/200	, ,	Mea	n 3.5%	SD	3.42%
*Lung: Alveolar/Bronchiolar Carcino	oma					••••••							•••••	
		1/50 1/50	(2%) (2%)	1/49	(2%)	0/50	(0%)		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	3/199	(1.51%)	Mean	1.51%	SD	1.01%	Total	0/200	(0%)	Mea	n 0%	SD	0%
*Lung: Alveolar/Bronchiolar Carcino Adenoma Overall Incidence	oma or Alv	4/50 4/50 1/50 10/199	(8%) (2%)	2/49 Mean	(4%) 5.02%	3/50 SD	(6%) 2.57%	Total	1/50 2/50 7/200	(2%) (4%) (3.5%)	0/50 Mea	(0%) n 3.5%	4/50 SD	(8%) 3.42%
*Lung: Fibrosarcoma		0/50	(0%)	0/49	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/50 0/199	(0%) (0%)	Mean	0%	SD	0%	Total	0/50 1/200	(0%) (0.5%)	Mea	n 0.5%	SD	1%
*Lung: Hemangiosarcoma	• • • • • • • • • • • • • • • • • • • •						•••••					•••••	•••••	
. .		1/50 0/50	(2%) (0%)	0/49	(0%)	0/50	(0%)		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/199	(0.5%)	Mean	0.5%	SD	1%	Total		(0%)	Mea	n 0%	SD	0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 25

			Male				Female	
Lung: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lung: Squamous Cell Carcinoma	•••••							
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Lymph Node: Hemangiosarcoma								
·		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Mammary Gland: Adenolipoma	•••••			•••••				
·		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Mammary Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 2/50 (4%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	4/200 (2%)	Mean 2%	SD 2.31%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 26

			Male				Female	
Mammary Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		4/50 (8%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	5/200 (2.5%)	Mean 2.5%	SD 3.79%
Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		4/50 (8%) 2/50 (4%)	3/50 (6%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	9/200 (4.5%)	Mean 4.5%	SD 3.42%
Mammary Gland: Fibroadenoma								
		4/50 (8%) 1/50 (2%)	0/49 (0%)	0/50 (0%)		26/50 (52%) 21/50 (42%)	24/50 (48%)	17/50 (34%)
Overall Incidence	Total	5/199 (2.51%)	Mean 2.5%	SD 3.79%	Total	88/200 (44%)	Mean 44%	SD 7.83%
Mammary Gland: Fibroma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Mammary Gland: Fibroma, Fibroadenoma or								
		4/50 (8%) 1/50 (2%)	0/49 (0%)	0/50 (0%)		26/50 (52%) 22/50 (44%)	25/50 (50%)	17/50 (34%)
Overall Incidence	Total	5/199 (2.51%)	Mean 2.5%	SD 3.79%	Total	90/200 (45%)	Mean 45%	SD 8.08%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 27 Report Date: 04/29/2009

Species: RATS Strain: F344 Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Mammary Gland: Fibroma, Fibroadenoma,	Carcinoma, o	or Adenoma						
.,,	,	4/50 (8%) 1/50 (2%)	0/49 (0%)	0/50 (0%)		28/50 (56%) 22/50 (44%)	26/50 (52%)	17/50 (34%)
Overall Incidence	Total	5/199 (2.51%)	Mean 2.5%	SD 3.79%	Total	93/200 (46.5%)	Mean 46.5%	SD 9.71%
#Mesentery: Fibrosarcoma					•••••			
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma					•••••			
- -		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mesentery: Lipoma								
-		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mesentery: Rhabdomyosarcoma					•••••			
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 28

			Male				Female	
Nose: Adenoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Nose: Chondroma						•••••		
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Nose: Squamous Cell Carcino								
		0/50 (0%) 1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa, Papilloma Squamous o	Tongue, Phary	nx, Tooth, Gingiva):						
	·	0/50 (0%) 0/50 (0%)	1/49 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Oral Cavity (Oral Mucosa, Squamous Cell Carcino	Tongue, Phary							
- 		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 29

Report Date: 04/29/2009

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or **Papilloma** (2%)1/49 1/50 (2%)0/50 0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 2% Total 3/199 (1.51%) Mean 1.51% SD 1.01% Total 2/200 (1%) Mean 1% **#Oral Mucosa:** Squamous Cell Carcinoma 1/50 (2%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)(0%)(0%) 0/50 0/50 SD 1% SD 1% Overall Incidence Total 1/199 (0.5%) Mean 0.5% Total 1/200 (0.5%) Mean 0.5% **#Oral Mucosa: Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%) 0/50 0/50 **Overall Incidence** Total 2/199 (1.01%) Mean 1.01% SD 1.17% Total 0/200 (0%) Mean 0% SD 0% *Ovary: Cystadenoma 0/50 1/50 (2%)0/50 (0%)0/50 (0%)1/200 (0.5%) SD 1% **Overall Incidence** Total Mean 0.5% *Ovary: **Granulosa Cell Tumor Benign** 0/50 0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Page: 30

Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Male			Female	
*Ovary: Granulosa Cell Tumor Malignant				
C. a. a. soa oo a aa		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%
*Ovary:				
Granulosa Cell Tumor: Benign, Malignant, NOS		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Ovary:	•••••			
Granulosa-Theca Tumor Benign		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%
*Ovary:				
Granulosa-Theca Tumor Malignant		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%
*Ovary:				
Tubulostromal Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 31

			Male				Female	
Pancreas: Adenoma								
		7/50 (14%) 2/50 (4%)	1/49 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	11/199 (5.53%)	Mean 5.51%	SD 5.74%	Total	0/200 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma				•••••				
		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma or Adenoma								
		8/50 (16%) 2/50 (4%)	1/49 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	12/199 (6.03%)	Mean 6.01%	SD 6.72%	Total	0/200 (0%)	Mean 0%	SD 0%
Pancreas: Mixed Tumor Benign								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Pancreas: Mixed Tumor Malignant								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 32

			Male				Female	
Parathyroid Gland: Adenoma								
		0/47 (0%) 1/49 (2%)	1/49 (2%)	1/45 (2%)		0/47 (0%) 2/46 (4%)	0/44 (0%)	0/47 (0%)
overall Incidence	Total	3/190 (1.58%)	Mean 1.58%	SD 1.05%	Total	2/184 (1.09%)	Mean 1.09%	SD 2.17%
Peripheral Nerve: Schwannoma Malignant					•••••			
_		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Peripheral Nerve: Schwannoma: Benign, Mal								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Distalis Adenoma								
		19/50 (38%) 11/50 (22%)	21/49 (43%)	6/50 (12%)		25/50 (50%) 27/50 (54%)	29/50 (58%)	25/50 (50%)
Overall Incidence	Total	57/199 (28.64%)	Mean 28.71%	SD 14.27%	Total	106/200 (53%)	Mean 53%	SD 3.83%
Pituitary Gland: Pars Distalis Carcinoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female					
Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma												
		19/50 (38%) 11/50 (22%)	21/49 (43%) 6/5	50 (12%)		25/50 (50%) 27/50 (54%)	30/50 (60%)	25/50 (50%)				
Overall Incidence	Total	57/199 (28.64%)	Mean 28.71%	SD 14.27%	Total	107/200 (53.5%)	Mean 53.5%	SD 4.73%				
*Pituitary Gland: Pars Dista Ganglioneuroma												
		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/5	50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%				
*Pituitary Gland: Pars Interr Adenoma	nedia:				•••••							
		1/50 (2%) 0/50 (0%)	0/49 (0%) 0/5	50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%				
*Pituitary Gland: Pars Interr Carcinoma	nedia:				•••••							
		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/5	50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%				
*Pituitary Gland: Pars Interr Carcinoma or Adenoma	nedia:											
		1/50 (2%) 0/50 (0%)	0/49 (0%) 0/5	50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

Page: 33

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 34

			Male				Female	
*Prostate: Adenoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%				
Prostate: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%				
'Salivary Glands: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Seminal Vesicle: Adenoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%				
Skeletal Muscle: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 35
Report Date:04/29/2009

			Male				Female	
Skeletal Muscle: Hemangioma								
_		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skeletal Muscle:								
•		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma	•••••							
•		0/50 (0%) 0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma or l								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

AGE

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Skeletal Muscle: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Adenoma					•••••	•••••	•••••	
		0/50 (0%) 0/50 (0%)	2/49 (4%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.02%	SD 2.04%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Skin: Basal Cell Adenoma or B	asosquamou	0/50 (0%)	2/49 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/50 (0%) 2/199 (1.01%)	Mean 1.02%	SD 2.04%	Total	0/50 (0%) 1/200 (0.5%)	Mean 0.5%	SD 1%
Skin: Basal Cell Adenoma, Bas Trichoepithelioma	osquamous `	Tumor Benign, or 0/50 (0%)	2/49 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	2/49 (4%)	,		0/50 (0%)	0/30 (0%)	,
Overall Incidence	Total	2/199 (1.01%)	Mean 1.02%	SD 2.04%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Skin: Basal Cell Carcinoma								
		1/50 (2%) 0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

Page: 36

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 37

				Male				Female			
Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)											
Noo,		1/50 0/50	(2%) (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total		(1.01%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%		
#Skin: Basal Cell Carcinoma, Tumor (benign, maligr	Basal Cell Ader	noma, Basc	osquamous	2/49 (4%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)		
		0/50	(0%)	,	,		0/50 (0%)	,	,		
Overall Incidence	Total	4/199	(2.01%)	Mean 2.02	% SD 1.67%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%		
	inoma, Carcinon oma, Adenoma,	na, Basosq Papilloma, pithelioma	ı. Tumor (M Sq								
#Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan	inoma, Carcinon oma, Adenoma, tthoma, Trichoe	na, Basosq Papilloma, pithelioma 8/50 3/50	1. Tumor (M Sq (16%) (6%)	2/49 (4%)	3/50 (6%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	1/50 (2%)		
#Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan Overall Incidence	inoma, Carcinon oma, Adenoma, ithoma, Trichoe Total	na, Basosq Papilloma, pithelioma 8/50 3/50 16/199	(16%) (6%) (8.04%)	2/49 (4%) Mean 8.02	% SD 5.4%	Total	1/50 (2%) 2/200 (1%)	Mean 1%	SD 1.15%		
#Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan Overall Incidence	inoma, Carcinon oma, Adenoma, ithoma, Trichoe Total	na, Basosq Papilloma, pithelioma 8/50 3/50 16/199	(16%) (6%) (8.04%)	2/49 (4%) Mean 8.02	% SD 5.4%		1/50 (2%) 2/200 (1%)	Mean 1%	SD 1.15%		
or B), Basal Cell Adend Papilloma, Keratoacan Overall Incidence #Skin:	inoma, Carcinon oma, Adenoma, ithoma, Trichoe Total	na, Basosq Papilloma, pithelioma 8/50 3/50 16/199	(16%) (6%) (8.04%)	2/49 (4%) Mean 8.02	% SD 5.4%		1/50 (2%) 2/200 (1%)	Mean 1%	SD 1.15%		
#Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan Overall Incidence #Skin: Fibroma Overall Incidence	inoma, Carcinon oma, Adenoma, ithoma, Trichoe Total	na, Basosq Papilloma, pithelioma 8/50 3/50 16/199 5/50 3/50 18/199	(16%) (6%) (8.04%) (10%) (6%) (9.05%)	2/49 (4%) Mean 8.02 7/49 (14%) Mean 9.07	% SD 5.4%) 3/50 (6%) % SD 3.95%	Total	1/50 (2%) 2/200 (1%) 0/50 (0%) 3/50 (6%) 6/200 (3%)	Mean 1% 1/50 (2%) Mean 3%	SD 1.15% 2/50 (4%) SD 2.58%		
#Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan Overall Incidence #Skin: Fibroma Overall Incidence	inoma, Carcinon oma, Adenoma, ithoma, Trichoe Total	na, Basosq Papilloma, pithelioma 8/50 3/50 16/199 5/50 3/50 18/199	(16%) (6%) (8.04%) (10%) (6%) (9.05%)	2/49 (4%) Mean 8.02 7/49 (14%) Mean 9.07	% SD 5.4%) 3/50 (6%)	Total	1/50 (2%) 2/200 (1%) 0/50 (0%) 3/50 (6%) 6/200 (3%)	Mean 1% 1/50 (2%) Mean 3%	SD 1.15% 2/50 (4%) SD 2.58%		
#Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan Overall Incidence #Skin: Fibroma Overall Incidence #Skin: Fibroma	inoma, Carcinon oma, Adenoma, ithoma, Trichoe Total	na, Basosq Papilloma, pithelioma 8/50 3/50 16/199 5/50 3/50 18/199	(16%) (6%) (8.04%) (10%) (6%) (9.05%)	2/49 (4%) Mean 8.02 7/49 (14%) Mean 9.07	% SD 5.4%) 3/50 (6%) % SD 3.95%	Total	1/50 (2%) 2/200 (1%) 0/50 (0%) 3/50 (6%) 6/200 (3%)	Mean 1% 1/50 (2%) Mean 3%	SD 1.15% 2/50 (4%) SD 2.58%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Page: 38
Report Date: 04/29/2009

Species: RATS Strain: F344

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
#Skin: Fibrosarcoma								
		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
≄Skin: Fibrosarcoma, Sarcoma,						•••••	•••••	
Histiocytoma		2/50 (4%) 0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Skin: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Hemangiosarcoma						•••••	•••••	
-		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 39

			Male				Female	
Skin:								
Keratoacanthoma		7/50 (14%) 3/50 (6%)	0/49 (0%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	12/199 (6.03%)	Mean 6%	SD 5.89%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Lipoma				•••••				
		2/50 (4%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.51%	SD 1.92%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma								
·		0/50 (0%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Neural Crest Tumor				•••••			•••••	
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Neural Crest Tumor, Ma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 40

			Male				Female	
Skin: Neurofibroma or Schwan	noma benign							
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin:								
Neurofibrosarcoma or So	chwannoma (r	,						
		0/50 (0%) 3/50 (6%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 3%	Total	0/200 (0%)	Mean 0%	SD 0%
Neurofibrosarcoma, Neu malignant or NOS)	rofibroma, or	, ,						-4
malignant or NOS)	r ofibroma, or Total	0/50 (0%) 3/50 (6%) 3/199 (1.51%)	0/49 (0%) Mean 1.5%	0/50 (0%) SD 3%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
malignant or NOS)	ŕ	0/50 (0%) 3/50 (6%)	0/49 (0%)	,	Total	0/50 (0%)	(333)	(,
malignant or NOS) verall Incidence Skin:	ŕ	0/50 (0%) 3/50 (6%)	0/49 (0%)	,	Total	0/50 (0%)	(333)	(,
malignant or NOS)	ŕ	0/50 (0%) 3/50 (6%) 3/199 (1.51%) 1/50 (2%)	0/49 (0%)	,	Total	0/50 (0%) 0/200 (0%) 	(333)	(,
malignant or NOS) verall Incidence Skin: Sarcoma	ŕ	0/50 (0%) 3/50 (6%) 3/199 (1.51%)	0/49 (0%) Mean 1.5%	SD 3%	Total Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
malignant or NOS) Everall Incidence Skin: Sarcoma Everall Incidence	Total	0/50 (0%) 3/50 (6%) 3/199 (1.51%) 1/50 (2%) 0/50 (0%)	0/49 (0%) Mean 1.5% 0/49 (0%)	SD 3%		0/50 (0%) 0/200 (0%) 	Mean 0%	SD 0% 0/50 (0%)
malignant or NOS) Overall Incidence Skin: Sarcoma Overall Incidence	Total	0/50 (0%) 3/50 (6%) 3/199 (1.51%) 1/50 (2%) 0/50 (0%) 2/199 (1.01%)	0/49 (0%) Mean 1.5% 0/49 (0%) Mean 1%	SD 3% 1/50 (2%) SD 1.15%		0/50 (0%) 0/200 (0%) 0/50 (0%) 0/50 (0%) 0/200 (0%)	Mean 0% 0/50 (0%) Mean 0%	SD 0% 0/50 (0%) SD 0%
malignant or NOS) Overall Incidence Skin: Sarcoma Overall Incidence	Total	0/50 (0%) 3/50 (6%) 3/199 (1.51%) 1/50 (2%) 0/50 (0%)	0/49 (0%) Mean 1.5% 0/49 (0%)	SD 3%		0/50 (0%) 0/200 (0%) 	Mean 0%	SD 0% 0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 41

Report Date:04/29/2009

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skin: Schwannoma Malignant								
•		0/50 (0%) 3/50 (6%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 3%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinom	a		•••••			•••••		
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinom Basosquamous Tumor (m	nalignant or N	1/50 (2%) 0/50 (0%)	0/49 (0%)	1/50 (2%)	-	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma	l	0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	(,		1/50 (2%)	0/30 (0%)	()
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Squamous Cell Papilloma	or Papillom	a	•••••			•••••		
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 42

Report Date:04/29/2009

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female	
#Skin: Squamous Cell Papillo Carcinoma or Keratoad		Squamous Cell					
		7/50 (14%) 3/50 (6%)	0/49 (0%)	2/50 (4%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/5	50 (0%)
Overall Incidence	Total	12/199 (6.03%)	Mean 6%	SD 5.89%	Total 1/200 (0.5%)		SD 1%
#Skin:							
Squamous Cell Papillo	oma, Papilloma,	or Keratoacanthoma 7/50 (14%) 3/50 (6%)	0/49 (0%)	2/50 (4%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/9	50 (0%)
Overall Incidence	Total	12/199 (6.03%)	Mean 6%	SD 5.89%	Total 1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Trichoepithelioma							
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/5	50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total 0/200 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma							
		1/50 (2%) 0/50 (0%)	0/49 (0%)	1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/5	50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 1.15%	Total 0/200 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma							
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/5	50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total 0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

II. Way2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 43

			Male				Female	
Skin: Sebaceous Gland: Carcinoma or Adenoma								
		1/50 (2%) 0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
Spinal Cord: Astrocytoma Benign								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Spinal Cord: Astrocytoma Malignant				•••••		•••••		•••••
, ,		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Spinal Cord: Glioma Malignant				•••••		•••••		•••••
-		0/50 (0%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%
Spleen: Fibrosarcoma	•••••				•••••			
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 44

Report Date:04/29/2009

Contract/Lab: All Laboratories Species: RATS Strain: F344

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
Spleen: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
pleen: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Spleen: Hemangiosarcoma	•••••							
-		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 2/50 (4%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	2/200 (1%)	Mean 1%	SD 2%
pleen: Leiomyosarcoma						•••••		
•		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Spleen: Sarcoma					•••••			
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

II. Way2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 45

			Male				Female	
#Stomach, Forestomach: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma					•••••			
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma o Overall Incidence	or Papillon Total	na Squamous 0/50 (0%) 0/50 (0%) 0/199 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/50 (2%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	0/50 (0%) SD 1%
Stomach, Forestomach: Squamous Cell Papilloma		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)	•••••	0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Stomach, Glandular: Lipoma					• • • • • • • • • • • • • • • • • • • •			
•		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

11. May2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 46

			Male				Female	
#Stomach, Glandular: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Testes: Adenoma								
		46/50 (92%) 46/50 (92%)	37/49 (76%)	47/50 (94%)				
Overall Incidence	Total	176/199 (88.44%)	Mean 88.38%	SD 8.63%				
Thymus: Sarcoma								
		0/47 (0%) 0/50 (0%)	0/48 (0%)	0/47 (0%)		0/47 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/192 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%
Thymus: Thymoma Benign								
, , , , , ,		0/47 (0%) 0/50 (0%)	0/48 (0%)	0/47 (0%)		0/47 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
overall Incidence	Total	0/192 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%
Thymus: Thymoma Malignant					•••••			
,		0/47 (0%) 0/50 (0%)	0/48 (0%)	0/47 (0%)		0/47 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/192 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Carcinoma

Overall Incidence

Overall Incidence

*Thyroid Gland: C-Cell: Carcinoma or Adenoma

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Female Male *Thymus: **Thymoma NOS** 0/47 (0%)0/48 (0%)(0%)0/47 (0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 **Overall Incidence** Total 0/192 (0%) Mean 0% SD 0% Total 0/196 (0%) Mean 0% SD 0% *Thymus: Thymoma: Benign, Malignant, NOS 0/47 (0%)0/47 (0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/192 (0%) Mean 0% SD 0% Total 0/196 (0%) Mean 0% SD 0% *Thyroid Gland: C-Cell: Adenoma 9/50 (18%)(16%)(24%)7/50 (14%)5/50 (10%)(10%)8/50 (16%)8/50 (16%) **Overall Incidence** (12.5%)SD 3% Total 37/199 (18.59%) Mean 18.58% SD 3.72% Total 25/200 Mean 12.5% *Thyroid Gland: C-Cell:

(0%)

(24%)

SD 6.72%

SD 6%

3/50

0/50

9/50

8/50

27/200

Total

Total

3/200 (1.5%)

(6%)

(0%)

(18%)

(16%)

(13.5%)

0/50

5/50

(0%)

(10%)

Mean 13.5%

Mean 1.5%

0/50

SD 3%

(0%)

(10%)

SD 4.12%

*: [Denominator	is number	of anim	als with	tissues	examined	l microscopic	ally
------	-------------	-----------	---------	----------	---------	----------	---------------	------

Total

Total

(12%)

(30%)

(16%)

(21.61%)

Mean 3%

(16%)

Mean 21.58%

(0%)

6/50

0/50

15/50

8/50

43/199

6/199 (3.02%)

Page: 47

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Thyroid Gland: Follicular Cell: Adenoma								
		1/50 (2%) 0/50 (0%)	1/49 (2%)	1/50 (2%)		/50 (0%) /50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.51%	SD 1.01%		00 (0.5%)	Mean 0.5%	SD 1%
*Thyroid Gland: Follicular Cell: Carcinoma								
		1/50 (2%) 0/50 (0%)	0/49 (0%)	2/50 (4%)		/50 (2%) /50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%	Total 1/20	00 (0.5%)	Mean 0.5%	SD 1%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
		2/50 (4%) 0/50 (0%)	1/49 (2%)	3/50 (6%)		/50 (2%) /50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	6/199 (3.02%)	Mean 3.01%	SD 2.58%		00 (1%)	Mean 1%	SD 1.15%
#Tissue NOS: Lipoma								
·		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		/50 (0%) /50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%		00 (0%)	Mean 0%	SD 0%
#Tissue NOS: Paraganglioma	•••••							
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		/50 (0%) /50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%		00 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

Page: 48

^{#:} Denominator is number of animals necropsied

711. Way 2000

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 49

			Male				Female	
#Tissue NOS: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Tongue: Squamous Cell Carcinoma								
•		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Tongue: Squamous Cell Carcinoma c	or Papillon		0/40 /00/	0/50 (00/)		0/50 (00/)	0/50 (00/)	4/50 (00)
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Tongue: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Tooth: Adamantinoma Malignant	•••••							
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

11. May2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 50

			Male				Female	
#Tooth: Odontoma		0/50 (00/)	0/40 /00/	0/50 (00/)		0/50 (00/.)	0/50 (00/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Urinary Bladder: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma or Papilloma								
•		0/50 (0%) 0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma								
• • • • • • • • • • • • • • • • • • •		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Leiomyosarcoma								
· ···· , · · · · · · · · · · · · · · · · · · ·		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 51

Report Date: 04/29/2009

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Urinary Bladder: Papilloma 0/50 0/49 (0%)(2%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 **Overall Incidence** Total 1/199 (0.5%) Mean 0.5% SD 1% Total 0/200 (0%) Mean 0% SD 0% #Uterus: Adenoma 0/50 (0%)(0%)(0%)0/50 (0%) **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% #Uterus: Carcinoma 0/50 (0%)0/50 (0%)(2%)0/50 (0%)**Overall Incidence** SD 1% Total 1/200 (0.5%)Mean 0.5% **#Uterus:** Deciduoma Benign (0%) 1/50 0/50 (0%)0/50 0/50 (0%)**Overall Incidence** (0.5%)Mean 0.5% SD 1% Total 1/200 #Uterus: Hemangioma (0%) 0/50 (0%)0/50 0/50 (0%)**Overall Incidence** Total 0/200 (0%)Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Tumor Incidence for Selected Control Animal Groups

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Route: GAVAGE Vehicle: CORN OIL Page: 52

	Male				Female	
Uterus:						
Hemangiosarcoma			0/50	(0%)	0/50 (0%)	0/50 (0%)
			0/50	(0%)	0,00 (0,70)	0/00 (0/0)
verall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%
			•••••	• • • • • • • • • • • • • • • • • • • •		
Uterus: Leiomyoma						
Loidinyonia			0/50	(0%)	0/50 (0%)	0/50 (0%)
			0/50	(0%)		
verall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%
Uterus:			•••••	• • • • • • • • • • • • • • • • • • • •		
Leiomyosarcoma						
			0/50 0/50	(0%) (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/200 (` '	Mean 0%	SD 0%
Uterus:						
Polyp Stromal			8/50	(16%)	7/50 (14%)	8/50 (16%)
			5/50	(10%)	(11,	(111,
Overall Incidence		Total		(14%)	Mean 14%	SD 2.83%
Uterus:						
Sarcoma Stromal						
			0/50 0/50	(0%) (0%)	1/50 (2%)	0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 53
Report Date: 04/29/2009

Species: RATS Strain: F344

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
Uterus: Sarcoma Stromal or Po	lyp Stromal							
						8/50 (16%) 5/50 (10%)	7/50 (14%)	8/50 (16%)
verall Incidence					Total	28/200 (14%)	Mean 14%	SD 2.83%
Jterus:								
Schwannoma Malignan	t					0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence					Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
······································								
Vagina:								
Polyp						1/50 (2%)	0/50 (0%)	0/50 (0%)
overall Incidence					Total	0/50 (0%) 1/200 (0.5%)	Mean 0.5%	SD 1%
Vagina:								
Sarcoma						0/50 (0%)	0/50 (0%)	0/50 (0%)
					-	0/50 (0%)	NA 00/	OD 00/
verall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
Zymbal's Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 54

	Male					Female			
#Zymbal's Gland: Carcinoma									
		2/50 (4%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
#Zymbal's Gland: Carcinoma or Adenoma			•••••						
		2/50 (4%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied